United States Department of Agriculture

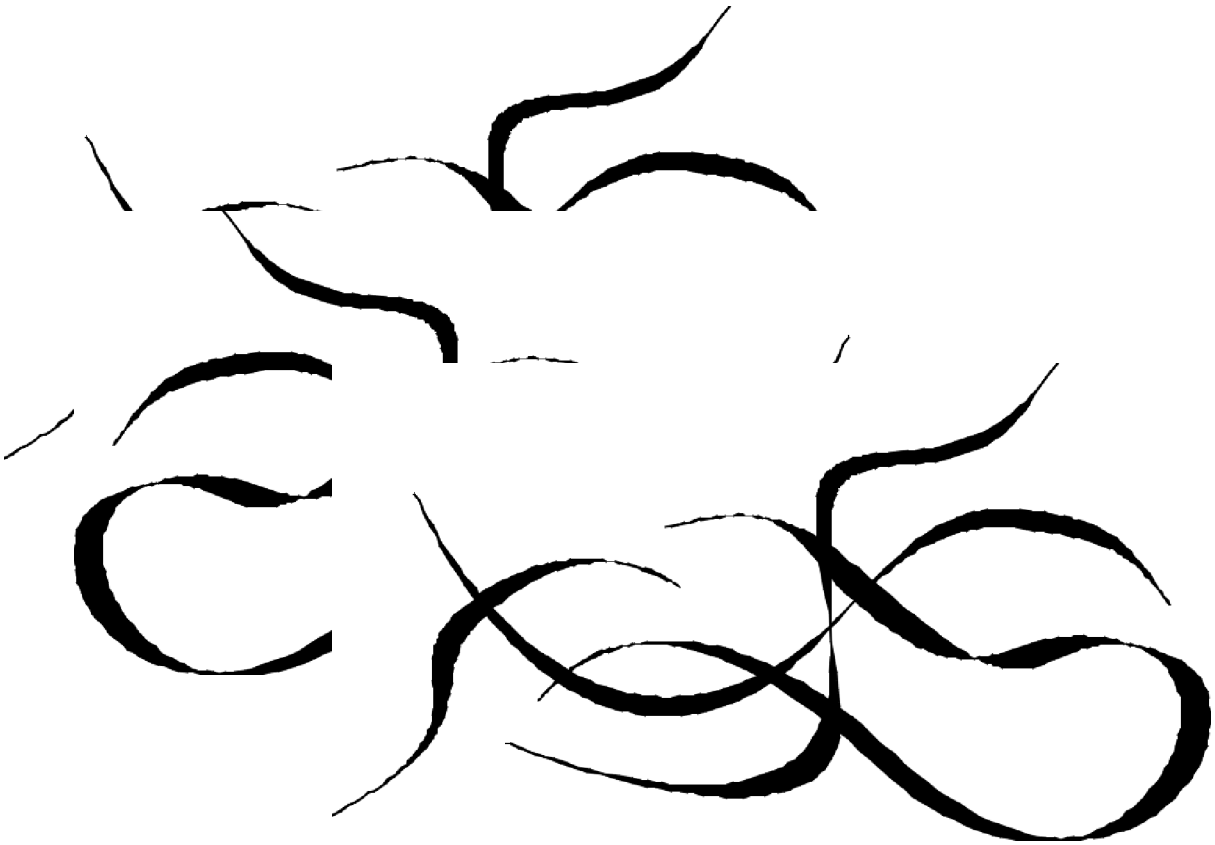
Agricultural Marketing Service

Fruit and Vegetable Programs

Processed Products Branch

"Qualified Through Verification"(QTV) Program for the Fresh-Cut Produce Industry

First Edition - 1999



February 1999

AGRICULTURAL MARKETING SERVICE
QUALIFIED THROUGH VERIFICATION (QTV) PROGRAM MANUAL

EXECUTIVE SUMMARY

The Agricultural Marketing Service (AMS), Fruit and Vegetable Program's (FV) Qualified Through Verification (QTV) program is a voluntary, user-fee, audit-based inspection service for producers of minimally processed fruits and vegetables. The program is designed to verify the suitability of a firm's food safety system. It is not a regulatory program. QTV empowers firms to apply science-based hazard analysis critical control point (HACCP) principles to identify hazards in their food manufacturing processes and take steps to prevent, reduce or eliminate risks associated with these hazards.

Under QTV, AMS reviews and assesses a firm's documented HACCP-based food safety QTV plan. After a plan is found to meet QTV program requirements, AMS uses on-site audits to determine the suitability of a firm's implementation of its plan. AMS auditors review records, observe and interview employees, conduct pre-operation sanitation inspections, and follow a specialized Systems Audit Checklist to verify that the company is following its QTV plan. Only companies that are able to meet existing good manufacturing and sanitation practices and that demonstrate that they are following their QTV plan, including adherence to the required HACCP-based techniques, are qualified to be in the program. QTV provides for reduced audit frequency when a facility has established a documented and verified food safety history. Firms in QTV meeting all program requirements may use the USDA QTV shield on packaging for products covered by the program.

This manual is intended to provide a description of the QTV program for potential applicants. AMS's new program for the fresh-cut produce industry offers its clients value-added incentives. The milestones that will lead a company towards completion of the program include:

Orientation and Hazard Analysis Critical Control Point (HACCP) Training
Successful Completion of an AMS Plant Survey
Comprehensive Hazard Analysis
Implementation of a HACCP Program with Suitable Critical Control Points
AMS Review of Company Plan and Prerequisite Programs
Validation Audit
Contract Agreement with AMS
Systems Audits for Verification by AMS
Microbiological Testing Program

AMS can provide companies involved with producing products that contain fresh-cut, minimally processed fruit or vegetable ingredients with the "Qualified Through Verification" inspection service to facilitate consistent distribution of safe, wholesome food products. Although the service focuses on continuous improvement in producing safe, wholesome food, this voluntary service can lead to substantial efficiencies in cost and personnel resources to the applicant.

Advertising and promotions must not misrepresent USDA, AMS, the QTV shield or suggest that only products bearing the shield are safe.

In addition to the criteria mentioned above, companies (herein referred to as applicants) interested in enrolling in this program must meet the following:

- Demonstrate a commitment by top management to QTV concepts and the scope of the program;

- Send personnel to approved HACCP training;

- Be "in production or service" at least four months of each year; and

- Successfully meet the Processed Products Branch Plant Survey requirements for current Good Manufacturing Practices (GMP's).

Following the guidelines in this manual does not excuse failure to comply with the Federal Food, Drug, and Cosmetic Act or any other applicable Federal, State, or Local laws or regulations.

Address inquiries to:

Chief, Processed Products Branch
Fruit and Vegetable Programs, AMS
U.S. Department of Agriculture
P.O. Box 96456, STOP 0247, South Building
Washington, DC 20090-6456
Phone: (202) 720-4693
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or e-mailed to james. rodeheaver@usda.gov.

TABLE OF CONTENTS

Page

PROGRAM SCOPE 1

DEFINITIONS 1

FEES 3

APPLICATION PROCESS 3

VALIDATION AUDIT 5

SYSTEMS AUDIT 6

MICROBIOLOGICAL TESTING IN THE FACILITY 8

AMS PROGRAM REVIEW AUDITS OF QTV 9

REPORTING AND DOCUMENTATION CONTROL 10

AMS QTV PLAN SUBMISSION GUIDE 11

FIGURES:

Figure 1 12

Figure 2 14

Figure 3 14

Figure 4 15

Figure 5 22

Figure 6 23

APPENDIX:

The Systems Audit Checklist, Appendix A 29

Systems Audit Checklist Reference, Appendix B 35

List of References, Appendix C 47

PROGRAM SCOPE:

QTV is a food safety program based on Hazard Analysis Critical Control Point (HACCP), Good Manufacturing Practices (GMP's), sanitation programs, product recall plan, and microbiological testing. The Agency has found that QTV fosters a proactive approach by the production facility's management for identifying process deficiencies during production rather than after production is completed.

The QTV program is funded entirely through user fees. Fees for the program would be provided for in the regulations under 7 Code of Federal Regulations (CFR) §52.5 1 (a). This fee is charged for the time required by AMS personnel to review company QTV plans, travel to and from an audit site, do the audit, and perform associated administrative activities. All work conducted by AMS is charged on an hourly basis.

DEFINITIONS: Most of the definitions[1] are the same as those established by the National Advisory Committee on Microbiological Criteria for Foods publication, "Hazard Analysis and Critical Control Point Principles and Application Guidelines," adopted August 14, 1997.

Audit Rating: The level achieved by an applicant based on their performance of a validation or systems audit. The audit rating is used to determine the facility rating.

Control Point: Any step in a process whereby biological, chemical, or physical hazards can be controlled .

Corrective Action: Procedures followed when a deviation occurs.

Critical Control Point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Deficiency: A deviation from the QTV Plan requirements or other conditions that have clear potential to lead to unsafe product or that bring into question the underlying commitment of the firm to the QTV program (e.g., falsified documents or interference with the audit).

Critical Limit: A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

Deviation: Failure to meet a critical limit.

Facility Rating: The level a facility achieves based on the results or audit rating of a validation or systems audit. The facility rating is used to determine the frequency of the audits.

1 Exceptions to this are definitions specific to the QTV Program.

Hazards: A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis Critical Control Point (HACCP): A systematic approach to the identification, evaluation, and control of food safety hazards.

Hazard Analysis Critical Control Point (HACCP) **Plan:** The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

Hazard Analysis: The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

HACCP-Certified Training: A two or three-day course with a training agenda and certificate from but not limited to the listing on the USDA/FDA database website: www.nal.usda.gov/fnic/foodborne/haccp/training.html.

Major Deficiency: A deviation from QTV plan requirements which may inhibit the maintenance of safety but does not result in unsafe product.

Minor Deficiency: A deviation in part of the QTV-based system relative to facility sanitation which is not likely to materially reduce the facility's ability to meet acceptable sanitation requirements.

Prerequisite Programs: Procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system.

Preventive or Control Measure(s): Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Process: One or more actions or operations to harvest, produce, manufacture, store, handle, distribute, or sell a product or a group of similar products.

Program Review Audit: Unannounced on-site AMS review of the effectiveness of AMS field inspection personnel in following established procedures for the QTV Program.

QTV Plan: a description of a company's processes and procedures to assure the production of safe, wholesome product HACCP, USDA and FDA criteria.

Serious Deficiency: A deviation from the QTV plan that will not result in unsafe product but is highly objectionable (e.g., modification of critical limits without approval, records not available for inspection).

Systems Audit: Unannounced on-site AMS audit of the company's effectiveness in following the QTV plan after the company has been validated.

Validation: The element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Validation Audit: Prearranged on-site AMS audit of the completeness and performance of a company's QTV plan, and the company's effectiveness in following the QTV plan.

Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

FEES

The Agricultural Marketing Act of 1946, as amended, provides AMS general authority for fee-for-service programs. The fee is based on the time required by AMS personnel to review company QTV plans for AMS acceptance and for travel to and from an audit site to conduct Validation and Systems Audits, audit time, and associated administrative activities. Currently, the door-to-door timeframe for a typical QTV systems audit and associated travel time, based on recently completed QTV systems audits by two auditors, runs between 30 to 45 hours. Costs for analytical work regularly performed by a firm or an outside provider to support a firm's QTV program is the firm's responsibility. AMS will make any necessary fee rate adjustments to ensure that fees are adequate to cover the costs of providing the service and are not excessive.

The overall cost of the QTV program for a participating firm is based on the frequency of the QTV audits. This frequency is based in turn on a firm's level of performance as determined by the periodic QTV audits. After validation, all firms begin at a "level four" rating which requires an unannounced QTV audit every two weeks. Under current QTV program requirements, a firm which demonstrates exemplary performance during all audits could advance from level four to level one in approximately seven months, or six audits, significantly reducing their costs. Level one currently requires an unannounced audit every three months. Alternatively, a firm that did only well enough to stay at level four would be audited by AMS every two weeks, which would significantly increase their costs to remain in the program.

APPLICATION PROCESS

A. **Initial contact:** Companies that wish to participate in this program may apply in writing to AMS at Processed Products Branch, Fruit and Vegetable Programs, AMS, U.S. Department of Agriculture, P.O. Box 96456, STOP 0247, South Building, Washington, DC 20090-6456. AMS will provide the applicant detailed information about the service through a formal presentation of the program to the company's senior management.

B. **AMS Plant survey:** Each company must satisfy and meet criteria described in an **AMS Plant Survey.**

C. **Employee training:** The company will also employ at least one HACCP-certified person knowledgeable in the QTV program's principles to be present **during all processing times**. Training for HACCP certification should include a minimum of 12 hours of instruction with a certificate issued upon completion. The HACCP certification must be

kept on file and available to AMS at all times. More than one HACCP-certified person will be needed to cover multiple shifts, vacations and periodic travel. The agenda must include the following topic areas: an overview of HACCP, hazard analysis, preventative measures, critical control point determination, sanitation SOP's, critical limits, monitoring procedures, corrective actions, recordkeeping, and how to develop a HACCP team and HACCP plan. A certificate of completion of training is required.

D. **QTV plan:** Each applicant develops its QTV plan (which includes prerequisites and HACCP plan) and submit it for review according to the QTV Review Procedures below.

The applicant's QTV plan may be drafted by its own staff or with assistance from outside consultants. The plan must include the following elements.

NOTE: More detail can be found in the attached Submission Guide (see page 15).

1. Organizational Chart and Organizational Chart Narrative
2. Description of Product and Labels
3. Process Flow Chart and Process Chart Narrative
4. Hazard Analysis
5. Critical Control Points Summary Table and Critical Control Point Narrative
6. Record Keeping Methods and CCP Logs and Forms
7. Sanitation Standard Operating Procedures and Good Manufacturing Practices (GMP's)
8. Microbiological Testing Program
9. Pest Control Program
10. Standard Operating Procedures (Optional)
11. Standard Testing Procedures (Optional)
12. Coding System and Recall Procedures
13. Customer Complaint Procedures
14. Employee Training Program for cGMPs, HACCP and Sanitation
15. Verification

E. **QTV Plan Review and Approval:** Submission and review of QTV plans will be handled using the following procedures:

1. Submit QTV Plans and procedures to AMS for review.

2. AMS will review the submitted plan and request any necessary changes.

F. **Pre-Validation Audit Period:** Prior to Validation of the company's QTV plan, the firm must operate using its approved plan for a minimum of 30 days. This allows the firm time to evaluate the effectiveness of its QTV plan and generate a record of processing history. This will also provide the AMS Validation team with necessary information regarding the company's ability to follow their own written procedures. For validation into the QTV program, a company must perform the following:

1. The company must begin following their QTV plan.

2. The company must adhere to the plan's provisions and keep all records associated with the approved QTV plan for at least 30 consecutive production days.

3. The company will contact the AMS as soon as they believe their plan is functioning successfully and when they have records covering at least thirty (30) consecutive production days.

4. AMS will schedule a date and time for the Validation audit with the company. Once the Validation audit is scheduled, AMS informs the company of its date and location.

G. **Modifications to the QTV plan:** After the QTV plan **has been approved,** modifications may be made under the following conditions:

1. The company **must notify AMS,** in writing (faxes are acceptable), of any modifications in their QTV plan **before implementing** the changes. AMS acknowledgment and response to the modification will be faxed promptly to the applicant.

2. Any changes made to the plan due to unusual circumstances, such as to address a health or safety issue, must be documented in a corrective action plan. AMS will assess the modifications for acceptability as appropriate and a confirmation of approval or recommended changes will be faxed to the applicant.

H. Verification that the company's hazard analysis is complete and that CCP's have been properly identified, is the first step toward AMS' Validation Audit.

VALIDATION AUDIT

The validation audit will determine if all of the critical control points have been identified, whether the plan is being followed and monitored by the company, and whether it is effectively controlling the identified hazards. This audit follows the 30-day pre-validation period when the firm operated under its approved plan. Typically, it takes three QTV auditors two or three days to conduct the validation audit. This is a complete review by AMS QTV auditors of the company's QTV plan in operation. The auditors will follow the Systems Audit Checklist, which is found in this manual. Procedures for validation are as follows:

1. The number and structure of the team will be determined by the size and complexity of the company's process.

2. The AMS audit team leader will have final authority of the facility's rating based on the teams findings. A consensus from all auditors is required on each deficiency.

3. Validation includes interviewing company employees, conducting paperwork reviews of prerequisite programs and the HACCP plan, recording sanitation and process observations, and the disposition of finished product.

4. Companies will be rated using the Systems Audit Checklist. If the company receives a Level IV or higher audit rating (see "Systems Audits" on page 9), it will qualify as a participant in the program and contractual arrangements may be finalized.

5. If a company passes its validation audit and enters into a contractual arrangement with AMS, packages of all designated products under review during the validation are eligible to bear the appropriate official marks or otherwise note participation in the QTV program.

6. To build a compliance history, all companies after validation will enter the program at a facility rating of Level IV. The results of subsequent systems audit ratings may allow changes in the facility rating and audit frequency.

SYSTEMS AUDITS

Once a company has entered a contractual agreement, AMS will conduct unannounced Systems Audits, at the frequency identified below, to determine the company's continued adherence to their plan.

The results of each Systems Audit is based upon the findings as recorded on the appropriate Systems Audit Checklist and will be used with the following criteria to determine the facility's next rating.

Systems Audit Frequency Schedule					
Facility Rating	Establishment Type	Number Of Deficiencies			
	Processors	Minor	Major	Serious	Critical
Level IV	1 visit/2 weeks	NA**	≥11	3-4	0
Level III	1 visit/1 month	≥7	6-10	1-2	0
Level II	1 visit/2 mos.	0-6	0-5	0	0
Level I	1 visit/3 mos.	0-6	0-5	0	0
For Facilities That Fall Below Level IV Facility Rating					
Level V	Daily as necessary	NA**	NA**	≥5	≥1

** NA = Not Applicable

A. Level IV - All applicants will enter the program at Level IV facility rating, regardless of the audit rating. A company will remain at a Level IV facility rating as long as they can maintain this level of performance, as defined in the table above, on each audit. After performing at a higher facility rating for two consecutive audits, at a bi-weekly frequency, the facility can achieve a Level III facility rating.

B. Level III - A company will remain at a Level III facility rating as long as they can maintain this level of performance, as defined in the table above, on each audit. After performing at a higher facility rating for two consecutive audits at a monthly frequency, the facility can achieve a Level II facility rating.

C. **Level II -** A company will remain at a Level II facility rating as long as they can maintain this level of performance, as defined in the table above, on each audit. After maintaining Level II facility rating for two consecutive bi-monthly audits, the facility can achieve a Level I facility rating status.

D. **Level I -** A company will remain at this facility rating as long as they can maintain this level of performance, as defined in the table above, on each quarterly audit frequency.

The QTV Audit Team will complete the Systems Audit Checklist in accordance with the instructions in Appendix A and Appendix B. The information recorded on the checklist is an indication of the company's performance in meeting its QTV plan, including its prerequisites.

Once a company has contracted for unannounced Systems Audits, AMS will periodically collect samples for laboratory analysis to contribute to the verification that microbiological hazards are under control.

E. **Procedures for Facilities That Fall Below Level IV Facility Rating:**

The spectrum of potential conditions under which a company may receive a critical deficiency varies such that it would be in the best interest of the public, industry, and AMS, not to specify the number of critical deficiencies permitted before AMS would withdraw QTV service. There may be conditions that would warrant withdrawal of service with one critical deficiency, such as, the willful shipment of product that could or would be harmful if consumed. Other conditions where, although critical deficiencies were received and the facility has undertaken vigorous corrective measures, there was no actual or imminent public harm may also warrant withdrawal of service with one critical deficiency.

An applicant receiving a Level V facility rating has demonstrated difficulties in administering their QTV Plan.

If a Systems Audit team determines that a facility has fallen to Level V, the team and the Officer-in-Charge (OIC) of the area field office will contact the chief of the Processed Products Branch (PPB) with their findings and recommendations.

A **final** decision will be made by the Chief and given to the Systems Audit team, which will report the decision orally and in writing to the company. The **final** decision will be made within one working day.

Facilities which fall to Level V or receive a critical deficiency at any time will be subject to accelerated audit schedule (daily or weekly) or the withdrawl of QTV status.

If the facility does not reach Level IV facility rating within the next audit, which may be as soon as the next day or next week, depending on the severity, AMS may withdraw its service and the use of the QTV mark. In deciding to withdraw service, AMS will treat each occurance, the severity of the deficiency, the surrounding circumstances, and the facility's response, on a case-by-case basis.

The following criteria will be used to determine if **daily or increased** auditing will be acceptable to AMS.

1. The applicant's senior management must submit in writing a Corrective Action Plan to AMS when an accelerated audit schedule is recommended. The Plan must detail how the facility will correct the problem and obtain a Level IV facility rating and include, at a minimum, detailed descriptions of the following:

    a.) A statement of the problem(s);
    b.) Identification of the person or persons responsible for correcting the situation;
    c.) The methods to be used to correct the problem(s);
    d.) A schedule which details the time frame to correct the problem.

2. AMS will review the corrective action plan submitted by the company.

3. The Plan will be accepted or rejected and AMS will notify the company. If accepted, AMS will tell the company how long they must remain on **daily or increased** auditing.

4. At the auditor's discretion, product compliance will be verified by end-item inspection.

5. A company dropped from the QTV program can reapply for the service. A re-validation audit will be required which includes a determination by AMS that all deficiencies have been corrected and that changes have been implemented to prevent recurrence.

MICROBIOLOGICAL TESTING IN THE FACILITY

A microbiological testing program is an important tool in monitoring the microbiological conditions of the facility and product throughout the entire production process. It is up to the company to design and implement a program that effectively addresses its processing situation. For example, the company must decide if testing will be in-house or performed by an outside laboratory, which types of testing methods to employ, which microorganisms to test for, what criteria and levels to set, etc. Testing can be accomplished by outside laboratories or in-house if there are suitable facilities and appropriate qualified staff.

The structure of the monitoring protocol of the microbial testing of the incoming product, equipment, environment, etc. is the responsibility of the plant management and should be designed for the specific facility. It is also the responsibility of the company to comply with all applicable state and federal regulations. A microbiological testing program shall, at least, address the following areas.

Incoming product; and

Equipment and environment.

Corrective actions when microbiological testing for targeted microorganisms prove positive for possible contamination.

The facility's microbiological testing program must be acceptable to AMS.

Incoming product testing can be used as a tool to verify the condition of the raw product received and create a history of reliability of the supplier’s ability to deliver sound product. One of the first steps in minimizing the microbial load is to receive and use product of the best condition.

Equipment and environmental testing can be used to monitor the overall performance of the company's sanitation procedures and processes. It can also be used as a gauge of the changes that can occur in a facility during processing especially when different types of products are produced.

A company must have corrective actions in place when test results are positive for the existence of a possible problem. It is the responsibility of the company to develop appropriate actions and be ready and able to initiate them when necessary. AMS auditors will review and evaluate these corrective actions as part of the systems audit.

AMS PROGRAM REVIEW AUDITS OF QTV

1. AMS will periodically verify that the QTV Program is functioning in accordance with established procedures through program review audits by PPB National Office. These audits are unannounced on-site reviews of the effectiveness of AMS field auditing personnel in following established procedures for the QTV Program.

2. The review audits will be performed by an AMS review team led by a qualified National office QTV auditor.

3. The audits will be performed, at least, once every two years for firms in the program.

4. During a Program Review Audit, the team will assist with the regular Systems Audits and provide feedback for continuous improvement.

5. The QTV Systems Auditors' facility rating shall agree with the facility rating given by the Program Review Team.

REPORTING AND DOCUMENTATION CONTROL

A. QTV Plan, and prerequisite programs:

All company QTV plans and company-generated QTV related materials are property of the applicant and AMS will treat them accordingly. It is our policy, that records and plans should be protected to the extent possible as provided by the Freedom of Information Act.

1. All company-related QTV materials will be marked **"confidential"** and stored in a secured area by AMS.

2. Copies of the QTV Plan may be made only under the following conditions:

   a. Each page must be stamped **"Confidential"** in red ink.

   b. All copies must be numbered.

   c. AMS will document which authorized individuals have checked out the QTV plan copy, the date of check out, and the date of return.

3. Only authorized personnel may receive a copy of the QTV plan.

4. Approved QTV plans of applicants dropped from the QTV program and unapproved QTV submissions, will be returned to the facility.

Systems Audit Reporting:

1. The completed Systems Audit Checklist (working papers, narrative, and supporting documentation included) will be sent to the Officer-in-Charge and the QTV Program Coodinator, by the Audit Team.

2. A copy of the completed Systems Audit Checklist (without the working papers) will be maintained by the Audit Team Leader.

3. A copy of the completed Systems Audit Checklist and report of its observations will be given to the company prior to exiting.

AMS QTV PROGRAM SUBMISSION GUIDE

This guide is designed to provide the potential applicant with an outline for developing a QTV plan. It provides the format that must be followed as well as brief discussions on each important point in the QTV plan. Every page of the QTV plan should be stamped **"Confidential."** QTV plans in AMS's possession remain the property of the company and are privileged or confidential.

The **plan must** be submitted in the following format. Also, please use **Figure 1** as a table of contents for your plan.

1. Organizational Chart and Organizational Chart Narrative
2. Description of Product and Labels
3. Process Flow Chart and Process Chart Narrative (See **Figure 5)**
4. Hazard Analysis
5. Critical Control Points Summary Table and Critical Control Point Narrative
6. Record Keeping Methods and CCP Logs and Forms
7. Sanitation Standard Operating Procedures and Good Manufacturing Practices (GMP's)
8. Microbiological Testing Program
9. Pest Control Program
10. Standard Operating Procedures (Optional)
11. Standard Testing Procedures (Optional)
12. Coding System and Recall Procedures
13. Customer Complaint Procedures
14. Employee Training Program for GMP's, HACCP and Sanitation
15. Verification

FIGURE 1

CONTENTS

1.	Organizational Chart and Organizational Chart Narrative
2.	Description of Product and Labels
3.	Process Flow Chart and Process Chart Narrative
4.	Hazard Analysis
5.	Critical Control Points Summary Table and Critical Control Point Narrative
6.	Record Keeping Methods and CCP Logs and Forms
7.	Sanitation Standard Operating Procedures & GMP's
8.	Microbiological Testing Program
9.	Pest Control Program
10.	Standard Operating Procedures (Optional)
11.	Standard Testing Procedures (Optional)
12.	Coding System and Recall Procedures
13.	Customer Complaint Procedures
14.	Employee Training Program for GMP's, HACCP and Sanitation
15.	Verification

1. Organizational Charts and Narrative

The facility must prepare an organization chart demonstrating the managerial responsibility of the company. This chart must show a chain of command within the management of the facility. The organizational chart must identify the organization of facility management to illustrate how the QTV program fits into the company's organization. The relationship between the position(s) responsible for the QTV program and the production manager(s) must be indicated.

The organizational narrative should explain how each position relates to the QTV program, its day-to-day operation, and the relation to the other positions on the chart.

2. Description of the Product(s) and Labels

Description of the Product(s): A description of the finished product (e.g., product form) must be developed in order to prepare a systematic evaluation of the hazards and associated risks in a specific food and its ingredients or components. The description should include the product specification, as it could affect the hazard analysis and any repacking processes that may be required. For example:

> Product Description: Shredded lettuce packed in food grade plastic bags, 6 oz. to 1 lb units; with an optimum shelf life of 9 days if refrigerated at 35°- 37°F; product distributed to foodservice and retail markets. Cases and plastic bags contains "use by" date. Product intended for consumption by general public and to be consumed directly from the container without washing or other preparation.

Originals or copies of all product labels, to include front and back panels, should be included in the QTV plan.

Label Specifications: Use of Department of Agriculture (USDA) "approved identification" with the QTV program is only allowed after a firm enters into a contract with AMS upon successful completion of the validation audit. The QTV mark may only be used on approved products included in QTV plan.

The QTV mark, used by an applicant operating under the QTV program shall be a shield using red, white, and blue background, similar in form and design to the examples below in Figures 2 and 3 or as approved by the Administrator.

←Blue →
←White→
←Red →

QTV No. 000

Figure 2

Figure 3

Approved firms must submit to AMS examples of all labels, packaging and advertising materials using the QTV mark for review.

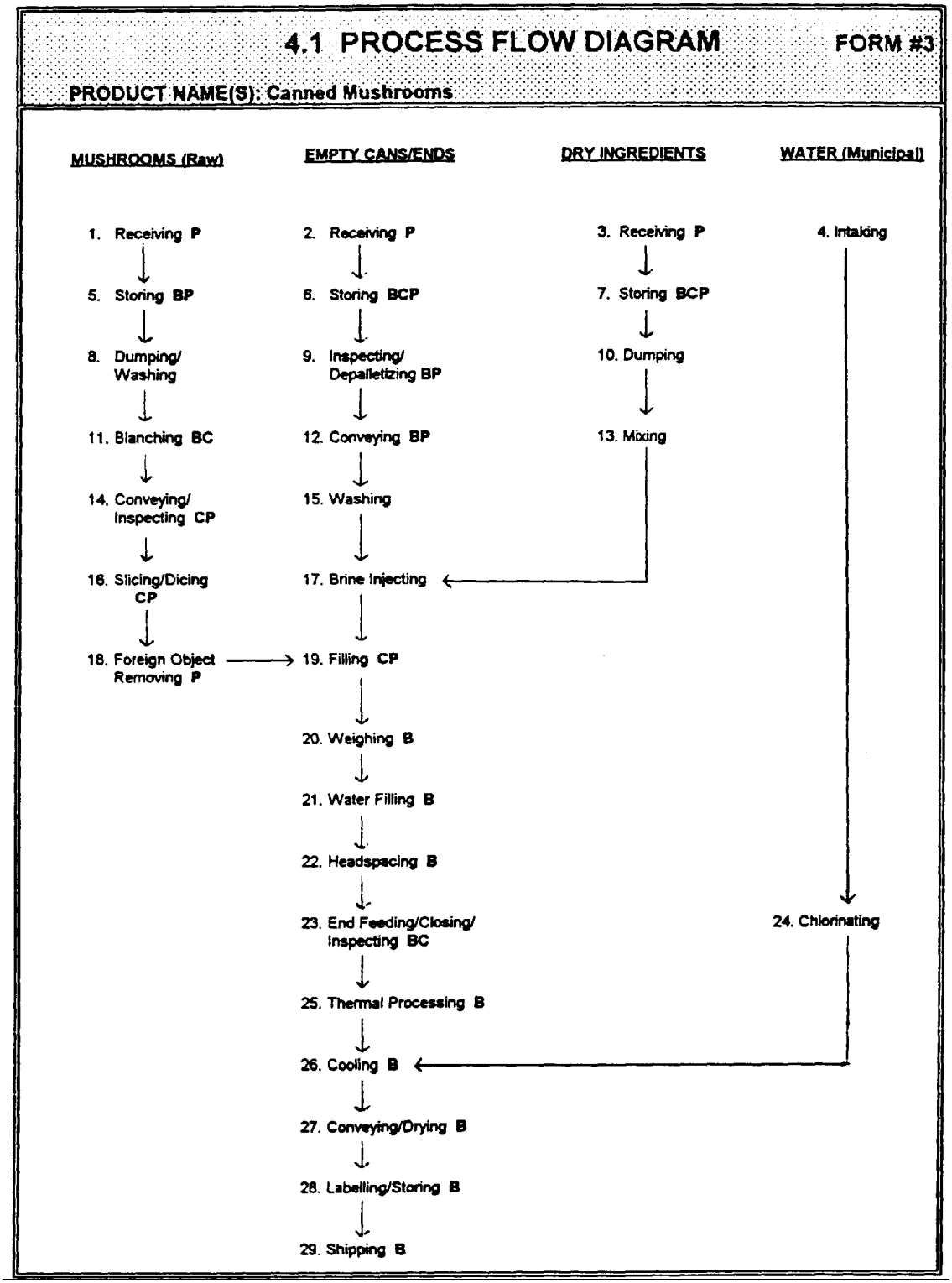
3. Process Flow Charts and Process Chart Narrative

To assist the plant in developing a QTV Plan, a process flow chart and description depicting the operational steps of how the processed product is handled throughout the plant must be made. The chart must show the steps in numerical order from when the firm takes control of the product until the firm releases control of the product. For example:

How is the product handled from receipt into the plant (e.g., is it stored in a refrigerator or is it in frozen condition)?
How is the product handled prior to processing (e.g., is the product thawed, fresh, chilled, frozen, etc.)?
How is the product handled on the processing line(s) (e.g., is it put on a conveyor belt, washed, peeled, sorted, sized, chilled, cooked, frozen, etc)?
How is the product stored?
How is it packaged?
How is it shipped?

The process chart narrative describes each operational step involved with a product or similar products with designations of critical control points. A process is defined as "one or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products". The process flow description should address all actions involved in the process. The company may design any type flow chart for their process. An example is shown below in **Figure 4.** Other examples of flow charts for various product forms may be obtained from AMS.

Figure 4
Example of Process Flow Chart.



4. Hazard Analysis

a. Identification of Hazards:

A thorough hazard analysis is one of the most important elements in developing a HACCP plan, and the QTV program requires firms to demonstrate that they have performed this step. A full discussion of the hazard analysis performed by a firm shall be included as part of the firm's QTV plan, or alternatively, a firm shall include a summary of the results of their hazard analysis in their QTV plan with a reference in the plan to the location of the full documentation of the hazard analysis performed.

There are numerous references in the literature which describe the hazard analysis process in varying levels of detail. Among these references are the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) "Hazard Analysis and Critical Control Point Principles and Application Guidelines" adopted August 14, 1997, the International Fresh-cut Produce Association's "Guidelines for Fresh-cut Produce Food Safety" and the Food and Drug Administration's 1997 Food Code. These and other references are important sources of information and guidance for performing a thorough hazard analysis. Firms should devote adequate resources and expertise to the hazard analysis process to ensure that it is comprehensive and exhaustive.

Whether temperature is a control factor at a critical control point is an issue being debated within the food safety community. Certainly, it is a good manufacturing practice for refrigerated foods. Recognizing the merits of both sides in the debate, AMS is modifying its QTV requirements so that a participating company may choose to control temperature of fresh-cut produce either as a CCP and part of the HACCP plan or as a regulatory control point and part of the GMP's and Standard Operating Procedures. Either way, AMS will require that temperature be addressed by the company in their comprehensive hazard analysis and AMS will expect a QTV facility to monitor temperature as a significant factor in the safety of fresh-cut produce.

A typical hazard analysis includes:

- Identifying factors which can contribute to food safety hazards for a product. These factors include, but are not limited to the nature of the product; the raw materials and ingredients from which it is produced; each step in the process from planting through to consumption by the consumer; equipment involved at each step; environmental conditions; and product packaging; etc.

- Identifying all potential biological, chemical or physical hazards which could affect the food safety of each product or group of similar products.

- Evaluating the each potential hazard to determine if it should be addressed in the HACCP plan. The severity of a potential hazard and the likelihood of its occurrence are factors which should be considered in determining whether a particular hazard should be addressed in the HACCP plan.

A hazard analysis must consider potential hazards at all stages of the product's development, starting from planting, growing and harvesting to transporting, storing and processing. This hazard analysis process identifies hazards that must be eliminated, reduced to a safe level or prevented in order to produce a safe product. Listed below are some examples of types of hazards that could affect the product.

Biological - Harmful bacteria and viruses

Chemical - Pesticide residue, acid, cleaners, sanitizers, food grade oil, allergens, etc.

Physical - Box staples, wood, glass, rocks, insects, metal, etc.

When identifying hazards, it may be helpful to ask some basic questions. For example:

Receiving-- Question: What is the product coming into the facility?
Answer: Fresh lettuce grown locally from a known supplier.

Question: What undesirable physical hazards and factors can be encountered?
Answer: Foreign material and toxic plants, etc.

Question: What undesirable chemical hazards and factors can be encountered?
Answer: Pesticide residue, toxic cleaning solutions, allergens, poisons, etc.

To begin the hazard analysis, identify all possible biological, chemical, and physical hazards that can be associated with product described in the product description. Next identify the steps in the process flow where the hazards can occur. These process steps or control points are actual locations in the facility whereby biological, chemical, or physical hazards may be controlled. Types of locations may include, but are not limited to:

Raw material receiving;
Chilling room;
Inspection table;
Processing room chiller;
Metal detector;
Filler/packaging;
Storing; and
Shipping/loading dock.

NOTE: Any thermal processes, used in the facility, must have been established by a qualified person(s) having expert knowledge acquired by appropriate training and experience in the processing of the product. If included in the company QTV Plan, any critical limits designed by the person(s) will be in writing and will be used in the monitoring of the processing step.

b. Critical Control Point Determination

Critical Control Points (CCP's) can now be determined once the potential hazards and preventative measures are identified. CCP's are those points in a facilities process where the hazards can be either prevented, eliminated, or reduced to acceptable levels. The determination of CCP's can typically include:

- Listing of hazards to be addressed in the HACCP plan;
- Identifying control measures (including preventative measures) for each hazard which can prevent, eliminate, or reduce the hazard to an acceptable level; and
- Identifying as CCP's those points in the process where control measures can be applied to prevent, eliminate, or reduce the hazard to an acceptable level.

5. Critical Control Points (CCP) Summary Table and Critical Control Point Narrative

Figures 5 and 6 are an examples of a chart and narrative formats for listing the elements of the HACCP plan and should be followed for QTV plan submission. **Figure 5** is an example of a worksheet and acts as a quick reference of all numbered CCP's and the information pertaining to that process. The table provides information in bullet form in the following required steps: CCP(location), Hazard, Preventive Measures, Critical Limits, Monitoring Procedures, Corrective Actions, Records and Verification. The CCP narrative is an extension of the summary table with each CCP having its own page. Each narrative is titled by its CCP number and area of concern. The narrative should cover everything found in the summary table and allows for a more in-depth explanation of the processes in each of the steps. **Figure 6** is an example of the narrative description for each CCP. The narrative should completely explain the following:

a. Preventive (Control) Measures

The preventive measures determined for each of the identified significant hazards. Preventive measures prevent, reduce, or eliminate a significant hazard. These measures can include:

Vendor certification of pesticide residue-free raw product;
Pesticide residue testing;
Purchasing specifications;
Maintenance of proper temperature;
Refrigeration maintenance;
Training programs for employees;
Calibration of equipment (scales, thermometers);
Proper time and temperature control;
Production scheduling;
Adherence to current Good Manufacturing Practices;
Physical inspection;
Scale and equipment calibration;

Certificate of water potability;
Proper packaging;
Supervisory checks; and
Inventory control.

Please note that employee training is a preventative measure that is paramount in launching and maintaining a HACCP plan. HACCP is built on the premise of having a pro-active or preventive system which identifies and corrects problems before the product is released from the facility. This takes trained employees equipped with the ability to recognize and prevent problems as they arise.

b. Establish Critical Limits

A critical limit is defined as an established point or range which must not be exceeded if a food hazard is to be controlled at a CCP. Under critical limits, show the "operating range" that is to be met (see **Figure 6).** There may be more than one critical limit for a CCP. If any one of those limits is out of tolerance, the process will be out of control and a potential hazard can exist.

The critical limit is used by the firm to signal the fact that a potential hazard/problem exists at a particular CCP. At this point, the firm will weigh the possible solutions and decide what to do to correct the problem.

Criteria most frequently utilized for limits include temperature, time, available chlorine, pH, titratable acidity, preservatives, salt concentration, water activity (A_w), and other criteria. Critical limits can be quantitative (i.e., a numerical value) or qualitative (e.g., evidence of decomposition as determined by an organoleptic evaluation). They can be a maximum, minimum, or range value. Many different types of limit information may be needed for control of a CCP.

It is important to establish reasonable critical limits that will ensure control of the potential hazard. The firm may want to set limits that are more stringent than regulatory limits or product purchasing specifications to ensure that product will be acceptable.

c. Establish Monitoring Procedures

Monitoring procedures are the scheduled evaluation and/or observations recorded by the firm to report the findings at each CCP. Monitoring results must be documented. Failure to exercise control of a CCP is a critical deficiency in the Program.

A critical deficiency is a serious deviation from Plan requirements that compromises the safety of the product. Because of the potentially serious consequences of a critical deficiency, monitoring procedures at each CCP must be effective.

Continuous monitoring is possible with some types of physical and chemical methods and should be applied. However, when this is not possible, it is necessary to establish monitoring intervals that will reliably indicate that the hazard is under control.

For each CCP, list the procedures to be used to monitor the control of that specific CCP. When listing these procedures be specific. List:

i. What is the monitoring procedure;
ii. Who will perform the procedures;
iii. The frequency at which the procedure will be followed; and
iv. Any associated criteria for the procedure. For example; sampling plans used, definitions of samples and/or lots, etc.

d. Establish Corrective Actions

Corrective Actions are defined as procedures to be followed when a deviation occurs. When critical limits are exceeded at a CCP, corrective actions must be taken to eliminate the problem created by the deviation. These actions must also ensure proper disposition of the product involved. Corrective action for each critical limit of a critical control point must be developed. This is due to variations in product and the diversity of associated deviations.

Corrective Actions will involve:

i. A statement of the problem (usually in an "If...then" format);
ii. Procedures for handling of the product;
iii. Identify the person responsible for the corrective action;
iv. Testing to establish the acceptability (if applicable);
v. Final disposition of the product; and
vi. Documentation and signatures.

e. Establish Records

For each CCP, records are created demonstrating that monitoring procedures and corrective actions are being followed. The types of records that would demonstrate adequate documentation that CCP's are being controlled are:

Records showing that CCP's are being monitored. **The critical** limit should be incorporated on the monitoring record as a constant reminder to the examiner or observer.

Records documenting deviations from the QTV plan and the corrective actions taken when critical limits are exceeded. These records should include disposition of the products(s) involved. If the decision is made to use the product, indicate under what conditions it was maintained pending evaluation. **All reports of corrective actions must be kept in a separate file or log with copies attached to the monitoring record where the problem occurred.**

Note: Records showing that instrumentation or other equipment necessary to the monitoring process has been properly checked for accuracy and reliability, and is being properly maintained should also be included.

f. Establish Verification Procedures

Verification consists of periodic review by the company to determine the overall effectiveness of its QTV plan.

Verification helps confirm that all hazards were identified and that the appropriate CCP's were selected and that the QTV plan is functioning properly. Verification measures may include:

i. Inspection of the facility as to conformance with the facility's QTV plan and established federal regulations;

ii. Records review, including daily review of all CCP's;

iii. Physical, chemical, and sensory examinations of product to ensure conformance with QTV plan criteria.

iv. Testing for conformance with microbiological criteria where established; and

v. Inspection of a contract laboratory to ensure that the samples received for analysis are being examined correctly.

A facility's verification of its QTV plan should involve substantial self-monitoring of critical control points and other areas. It may include analysis of the raw material or in-line environmental testing depending on the possibility of emerging problem areas.

Analysis can be performed in-house at the facility or the samples can be analyzed by a contract laboratory.

Figure 5
Example of Listing of Critical Control Points

Critical Control Point	Hazard	Preventative Measure(s)	Critical Limit	Monitoring Procedures	Corrective Action	Records	Verification

Figure 6
Example of Critical Control Point Narrative

Critical Control Point 4 - Metal Detector

Hazards:

Preventative Measures:

Critical Limit:

Monitoring Procedures:

Corrective Actions:

Records:

Verification:

6. Record Keeping Methods and CCP Log and Forms

Maintenance of all logs and forms is an essential part of the QTV program. Documentation provides a history and establishes that processes are in control. For auditing purposes it is crucial that documents be readily available for review. A detailed description of where documents are located and filed is required.

> Example: Documents for CCP5 are located in the QC manager's office, brown metal filing cabinet #3, drawer 3b.

All documents related to CCPs should be identified by their corresponding CCP number and document creation date. The CCP number identifies that the document is utilized for that particular area. The date acts as an identifier for revisions of the documents. Copies of all forms and documents that are used in the QTV program will be maintained in the QTV plan. A listing of all CCP logs and forms used in the program will aid the auditor when reviewing documentation. Developing an accurate record keeping system that demonstrates control over critical control points will:

a. Advise facility management and AMS of the performance of an applicant's QTV plan on a day-to-day basis.

b. Provide evidence of proper and safe operation.

c. Serve as a mechanism for indicating potentially serious problems and assisting the responsible individuals in the determination of proper corrective action.

An efficient filing system must be set up for all QTV-related records and forms. **CCP monitoring records, CCP deviation and corrective action records shall be maintained for a period of six months to one year after the shelf-life of the product; and records for prerequisite programs maintained for a period of one year**. Annual verification audits, which are an in-depth evaluation of the HACCP system to ensure that the prerequisite programs and HACCP plan are being implemented as designed, should be taken into account when considering record retention time periods. All of the records and forms in this filing system must be accessible to AMS at all times.

7. Sanitation Standard Operating Procedures

Equally important but distinct from the CCP's are the Sanitation Standard Operating Procedures (SSOP's). Applicants must also develop standard operating procedures for daily, weekly, and otherwise periodic sanitation practices and procedures at their facility. Standard operating procedures should be specific as to how sanitation practices are performed. The QTV plan should list who will perform these procedures, the frequency of the procedures, and any associated information. Standard operating procedures should be written with the following assessment areas in mind:

> Structure and Layout;
> Maintenance;
> Cleaning and Sanitizing;

Personnel;
Restrooms;
Water Supply;
Ice;
Chemicals;
Ventilation; and
Waste Disposal.

Monitoring procedures for the SSOP's should be established. These monitoring procedure should include who will perform the monitoring, the frequency of monitoring, and any forms or records used to document this monitoring.

All the above areas will be evaluated by AMS using the appropriate form(s) for the applicant's type of operation.

These sanitation assessment areas are cross-cutting throughout the facility. This is why the QTV-based Submission Guide has been developed to discuss items relating to "process" factors separately from "sanitation."

8. Microbiological Testing Program

This is a description of the applicant's microbiological testing procedures, used to monitor their process, product and sanitation techniques to determine if they are effective in controlling food safety hazards and comply with the applicable regulatory guidelines. The microbiological testing procedures may include:

The types of organisms being tested for;
The types of tests used and how to count the organisms;
In-house testing and outside laboratory testing;
Incoming product testing;
Environmental and equipment testing;
Finished product testing, if desired;
Sampling conventions that will be used; and
The baseline standards employed.

The corrective actions are the procedures the company will take when microbial testing finds contamination of product, equipment and facility, or that an established microbial threshold was exceeded. Such corrective steps should include, but are not limited to:

Sanitizing affected areas and equipment;
Reviewing processing and/or sanitation procedures;
Reviewing supplier records and area; and
Holding or destroying contaminating product.

AMS endorses the use of outside analytical laboratories for microbial testing and food safety training.

Please note, microbial testing may be an inadequate means to monitor a CCP. Test results are

usually available after the product is out of the facility's control. Testing can be used effectively, however, to verify that the processes and sanitation techniques are effective.

9. Pest Control Program

The Pest Control program should identify how a company is effectively managing pest control in their plant. It is important to identify who has the responsibility and the authority to implement, evaluate and make decisions regarding the pest control program. If an outside contractor for pest control is being used, the name of the company, their procedures and methods, how often do they return to check traps and a map of where all the traps have been placed, should be documented.

A pest control program shall include, but not limited to, the following:

* Sanitation, housekeeping and good manufacturing practices.
* Facility and grounds inspection and surveillance.
* Proper facility design, maintenance, and physical pest exclusion.
* Proper stock handling and warehousing techniques.
* Appropriate use of mechanical pest control techniques and trapping strategies.
* Proper selection and application of pesticidal chemicals.

Documentation shall be maintained to provide evidence that a pest control program is in operation, surveillance is on going and verification is taking place.

10. Standard Operating Procedures (Optional)

This section includes the procedures for monitoring critical control points and other processes in the QTV program if more detail is needed and it is referenced in the QTV plan. The purpose of this section is to give applicants the option of cataloging their procedures. The Standard Operating Procedures (SOP's) should include, but not limited to: details on the procedures for monitoring temperature, pH, chlorine, etc. Each SOP must identify the procedure, its location, equipment, method, documentation, accountable personnel and who will verify the SOP.

11. Standard Testing Procedures (Optional)

This section includes the methodology of the tests used to implement the SOP's. The purpose of this section is to give applicants the option of cataloging their test procedures and equipment. The Standard Testing Procedures (STP's) should include, but not limited to: details of the type of chlorine test used, type of thermometer used, etc. Each STP must identify the procedure or equipment and corresponding SOP.

12. Coding System and Recall Procedures

A detailed explanation of the plant's product coding system and an example of each type of code used should be included. Recall procedures for identifying, locating, and retrieving products is an important tool used by industry to protect their customers. The Food and Drug Administration (FDA) has provided guidelines which direct how recalls are initiated and carried out. A copy of the facility's recall program must be submitted along with the QTV plan.

Each recall program should contain a current written contingency plan for use in initiating and effecting a recall, coding strategy that makes positive lot identification possible, and a listing of product distribution records that are necessary to facilitate the location of recalled product. See 21 Code of Federal Regulations (CFR) Part 7 for more information and requirements.

13. Consumer Complaint Procedure

Develop a consumer complaint file and a standard operating procedure for handling consumer complaints. It is suggested that a matrix of the type of complaints be developed to illustrate the firms's adherence to their Consumer Complaint Procedures. A company must have a procedure to deal with customer complaints. AMS will not routinely review specific complaints, however, it may do so as a result of a food safety complaint or incident.

14. Employee Training Program

An overview of the organization's training program should be provided in the QTV plan. This should include type of training provided, frequency, and how training is documented. A comprehensive training program includes, but is not necessarily limited to, training in the areas of:

Current Good Manufacturing Practices (GMP's);
Sanitation;
Hazard Analysis Critical Control Point (HACCP); and
Qualified Through Verification (QTV).

The program should also emphasize each employee's role and responsibilities in these areas. In addition, retraining of employees should be addressed. The training program description should answer questions such as:

What determines the need for an employees retraining?
How is the retraining accomplished?
Is there documentation supporting the need for retraining?
When did retraining occur and is it documented?

15. Verification

There are three levels of verification that will strengthen a firm's reliability in the QTV program. These three verifications are daily, monthly or quarterly, and annually.

Daily: A supervisor not involved in documenting plant performance under the QTV plan, should verify all QTV-related records each day to ensure that the operating decisions made by plant personnel are consistent with QTV plan requirements and follow-up when inconsistencies occur. That supervisor should review any reports of critical limit deviations, follow-up corrective action reports, and ensure that the QTV plan is followed.

Monthly /Quarterly: This periodic review verifies the HACCP plan and other intermittent records. This particular type of verification is designed to verify the proper implementation of QTV controls and identify trends that might indicate problems.

Annually: The annual verification should review the QTV plan and verify that any changes to the plan have been identified and evaluated for effectiveness. The review should include, but is not limited to, the following records: prerequisite programs, SOP's, lists of product ingredients and suppliers, process flow charts, QTV record forms and filing procedures and the QTV plan.

The annual verification is also an evaluation of the overall HACCP program. The hazard analysis should be reevaluated thoroughly to determine:

Whether there are any new scientific data that impact upon the operation;

What progress has been made to provide data where questions are raised about potential hazards and the likelihood of their occurrence; and

Whether the best control methods are being applied in the proper context (prerequisite programs versus **CCP).**

The HACCP plan should be evaluated to verify that the appropriate critical limits are being applied. A report should be generated documenting that:

QTV controls have been verified;
Changes have been made to improve implementation; and
The QTV plan and related documents are up-to-date.

It is also recommended that re-signing and re-dating of the SOP's, hazard analysis, and the QTV plan to be done to document that this annual verification activity has been performed.

NOTE: A firm must have an adequate quality assurance program which can provide the infrastructure to support all the elements in the QTV program. Appropriate quality assurance operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

Appendix A
The Systems Audit Checklist

This document provides instructions for completing the Systems Audit Checklist. The Systems Audit Checklist will be used by AMS auditors during Validations and Systems Audits.

AMS auditors will perform a Validation or Systems Audit and note any deficiencies. Deficiency areas include a company's adherence to their QTV plan, completeness of records, and sanitation.

Complete the form as follows:

1. Enter the complete name and address of the firm in the **Name and Address of Facility Inspected** area.

2. Enter all of the owners (company or individuals) in the **Facility Owner** area.

3. Enter the associated products which are being Validated or Audited in the **Products Concerned** area. The associated products can be taken from the products list in the submitted plan.

4. Enter the names of all auditors that are taking part in the Validation or Systems Audit in the **Name and Number of Auditors** area.

5. If a representative from the firm or other individual is accompanying the AMS audit team during the validation or audit, enter the individual's name and title in the **Name and Title of Accompanying Individual** area.

6. Enter the Processed Products Branch (PPB) region where the facility is located in the **PPB Region** area.

7. Enter the State where the facility is located in the **State** area.

8. Enter the QTV facility number, if applicable, that has been assigned to the facility in the **Facility Number** area.

9. Enter the month, day(s), and year the Validation or Systems Audit has taken place in the **Date (mm/dd/yy)** area. If the validation or audit takes more than one day, include all of the dates in the appropriate areas.

10. Enter the phone number of the facility in the **Phone Number** area.

11. Each deficiency found during the validation or audit will be checked in the appropriate box on the Systems Audit Checklist. The weight of the deficiency (Minor, Major, Serious, Critical) **cannot** be changed. There are two areas on the Checklist that have two or more boxes. If a deficiency is found in that area the auditor must decide which to check.

For all items of the records review, use the following guidance for determining the weight of the deficiency, based on the percentage of records that were found to be inaccurate:

SERIOUS: equal to or greater than eight (8), but less than 10 percent of records; and

CRITICAL: equal to or greater than 10 percent of records.

12. An explanation for each box checked on the Systems Audit Checklist will be recorded under the **Systems Audit Listing of Observations** section. This explanation will list out each deficiency and include the specifics of the deficiencies. For example, if monitoring procedures are not being followed at several critical control points, the box under B., PROCEDURES, "Monitoring Procedures not followed" would be checked. "The Systems Audit Listing of Observations" would then have each instance of this deficiency noted in detail. This detail would include specifics such as the critical control point, person(s) not following the monitoring procedures, and references to the monitoring procedures in the plan.

13. Total the Minor, Major, Serious, and Critical boxes and/or circles that have been checked in the **SUMMARY: Total Deficiencies** area.

14. Check the applicable symbol **{□ and ( )}** in the **"Beginning Facility Rating Level"** area. Use the totals of the present audit to arrive at the **"Audit Rating Level"** and check the applicable symbol **{□ and ( )}** for the facility. Enter the new facility rating in the **"Final Facility Rating"** area and check the applicable symbol **{□ and ( )}**. The facility will be placed on a Systems Audit frequency by numbers as they correspond to the table on the checklist.

15. All AMS auditors will sign their names and enter the date in the **Auditor Signature and Date** area.

SYSTEMS AUDIT CHECKLIST

Name and Address of Facility Audited:	PPB Office:	
	State:	
	Facility Number:	
Facility Owner (Company or Individual):	Date (mm/dd/yy):	
Products Concerned:	Phone Number:	
Name of Auditors:		
Name and Title of Accompanying Individual:		

Minor Deficiency: A deviation in part of the QTV-based system relative to facility sanitation which is not likely to materially reduce the facility's ability to meet acceptable sanitation requirements.
Major Deficiency: A deviation from QTV plan requirements which may inhibit the maintenance of safety but does not result in unsafe product.
Serious Deficiency: A deviation from the QTV plan that will not result in unsafe product but is highly objectionable (e.g., modification to critical limits without approval, or certified trained personnel not available).
Critical Deficiency: A deviation from the QTV plan requirements or other conditions that have clear potential to lead to unsafe product or that bring into question the underlying commitment of the firm to the QTV program (e.g., falsified documents, or interference with the audit).

Adherence to QTV Plan

		MIN	MAJ	SER	CR
A.	RECORDS				
1.	Records are not up-to-date.		☐	☐	
2.	Records are inaccurate.			☐	☐
3.	Records are not available for inspection.			☐	☐
4.	Any documents or records are falsified.			☐	☐
B.	PROCEDURES	MIN	MAJ	SER	CR
1.	Preventive Measures not followed.		☐		
2.	Monitoring Procedures not followed.			☐	
3.	Corrective Action not taken.			☐	☐
C.	OTHER	MIN	MAJ	SER	CR
1.	Modification to QTV plan used without approval.		☐		
2.	Modification to critical limits without approval.			☐	☐
3.	Certified trained personnel not available.			☐	
4.	QTV Plan Prerequisite Programs and/or Procedures not followed		☐	☐	☐

Facility Sanitation

		MIN	MAJ	SER	CR
1.	PEST CONTROL				
1.1	Harborage and attractant areas present.		☐		

1.2	Pest control measures not effective. 1.2.1 Exclusion		☐		
	1.2.2 Extermination			☐	
2.	STRUCTURE AND LAYOUT	MIN	MAJ	SER	CR
2.1	Grounds condition can permit contamination to enter the facility.	☐			
2.2	Facility 2.2.1 Design, layout, or materials used cannot be readily cleaned or sanitized; does not preclude contamination.		☐		
	2.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated.			☐	☐
2.3	Equipment and utensils' design, construction, location, or materials cannot be readily cleaned or sanitized; does not preclude product contamination.		☐		
3.	MAINTENANCE	MIN	MAJ	SER	CR
3.1	Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected. 3.1.1 Areas directly affecting product or primary packaging material.			☐	☐
	3.1.2 Other.	☐	☐		
3.2	Insufficient lighting.	☐			
3.3	Equipment and utensils not maintained in proper repair or removed when necessary. 3.3.1 Product contact surfaces.		☐	☐	
	3.3.2 Other.	☐	☐		
4.	CLEANING AND SANITIZING	MIN	MAJ	SER	CR
4.1	Product contact surfaces not cleaned and sanitized before use.			☐	☐
4.2	Non-product contact surfaces not cleaned before use.		☐	☐	
4.3	Inadequate housekeeping.	☐	☐		
4.4	Cleaning methods permit adulteration or contamination.			☐	☐
5.	PERSONNEL	MIN	MAJ	SER	CR
5.1	Processing or food handling personnel do not maintain a high degree of personal cleanliness.		☐	☐	
5.2	Processing or food handling personnel do not take necessary precautions to prevent contamination of food.			☐	☐
5.3	Controls. 5.3.1 Facility management does not have in effect measures to restrict people with known disease from contaminating the product.			☐	
	5.3.2 Hand washing and hand sanitizing stations not present or conveniently located.			☐	☐
6.	RESTROOMS	MIN	MAJ	SER	CR
6.1	Insufficient number of functional toilets.	☐			
6.2	Inadequate supplies.		☐		
7.	WATER SUPPLY	MIN	MAJ	SER	CR
7.1	Unsafe water supply.				☐
7.2	No protection against backflow, back-siphonage, or other sources of contamination.			☐	

7.3	Inadequate supply of hot water.	☐			
8.	ICE	MIN	MAJ	SER	CR
8.1	Not manufactured, handled, or used in a sanitary manner.			☐	☐
9.	CHEMICALS	MIN	MAJ	SER	CR
9.1	Chemical(s) improperly used or handled.			☐	☐
9.2	Chemical(s) improperly labeled.		☐		
9.3	Chemical(s) improperly stored.			☐	
10.	VENTILATION	MIN	MAJ	SER	CR
10.1	Condensation. 10.1.1 Areas directly affecting product or packaging material.			☐	☐
	10.1.2 Other.		☐		
10.2	Adequate air exchange does not exist.	☐			
11.	WASTE DISPOSAL	MIN	MAJ	SER	CR
11.1	Improper disposal of: 11.1.1 Sewage.			☐	☐
	11.1.2 Processing waste.			☐	

SUMMARY	MIN	MAJ	SER	CR
Total Deficiencies				

Beginning Facility Rating Level	Audit Rating Level	Final Facility Rating Level
☐ Level IV ( ) 0 audit above level ☐ Level III ( ) 1st audit above level ☐ Level II ( ) 2nd audit above level ☐ Level I	☐ Level IV ☐ Level III ☐ Level II ☐ Level I	☐ Level IV ( ) 0 audit above level ☐ Level III ( ) 1st audit above level ☐ Level II ( ) 2nd audit above level ☐ Level I
Facilities That Fall Below Level IV Facility Rating		☐ Level V
Auditor Signature and Date		
Reviewer's Signature and Date		

Systems Audit Frequency Schedule					
Facility Rating	Establishment Type	Number Of Deficiencies			
	Processors	Minor	Major	Serious	Critical
Level IV	1 visit/2 weeks	NA**	≥11	4-5	0
Level III	1 visit/1 month	≥7	6-10	1-3	0
Level II	1 visit/2 mos.	0-6	0-5	0	0
Level I	1 visit/3 mos.	0-6	0-5	0	0
For Facilities That Fall Below Level IV Facility Rating					
Level V	Daily or as necessary	NA**	NA**	≥5	≥1

** NA = Not Applicable

Systems Audit
Listing of Observations

Date of Audit: ______________________________

List Deficiency Step and Classification	Reasons for Deficiency Classification (Minor/Major/Serious/Critical)

Appendix B

Systems Audit Checklist Reference

Adherence to QTV-based Plan

A. RECORDS

REASON:
Records are used to record the success of the facility's QTV system. Non-compliance in record keeping can make it difficult to prove control of the process.

1. Records are not up to date.

COMPLIANCE:
All records must be kept up-to-date. Entries must be made as they are measured. All time schedules outlined in the QTV plan must be maintained. Examples of non-compliance include: measurement observed to be taken but not entered on record; partial entry of information from monitoring procedures; initials for QA verification not recorded in a timely manner; etc. If records are not up-to-date, the **Major** box for this deficiency should be checked.

All labels must be up-to-date. All labels must be kept on file by the firm. If labels are not up-to-date, the **Serious** box for this deficiency should be checked.

2. Records are inaccurate.

COMPLIANCE:
All entries must be accurate or the record is meaningless. If calculations, time test measured, etc., are not correct, or illegible, the box for this deficiency should be checked. If incorrect entries are made on a record, a line must be drawn through it and the correct entry should be made with the initials of the writer. White-out (correction fluid) and pencils must not be used. This deficiency will also be used for the compliance of product leaving the company. If auditor finds records, deemed to be acceptable by the company, that are unacceptable, the deficiency will be checked at the following level (percentage of records verified):

SERIOUS: equal to or greater than 8, but less than 10 percent of records;
CRITICAL: equal to or greater than 10 percent of records.

3. Records are not available for inspection.

COMPLIANCE:
If the firm does not promptly provide the applicable records for review or records are misplaced, they are not in compliance with this item (SERIOUS). If portions of records are not available, the company **is** not in compliance with this item (CRITICAL).

4. Any documents or records are falsified.

COMPLIANCE:

If an item on a record was shown to be corrected with correction fluid or other means of obliteration, this will be considered an inaccurate entry. If records are falsified intentionally on the part of the company, this is CRITICAL.

B. PROCEDURES

REASON:

The procedures outlined in a company's QTV plan must be followed as written. The plan was approved by AMS as a whole, not procedure-by-procedure. Not following a procedure could affect the entire critical control point.

1. Preventive measures not followed.

COMPLIANCE:

Although no documentation is required, preventive measures provide a buffer for the company in keeping control of a particular critical control point. Not following these measures affects the other subsequent procedures at that critical control point. If any preventive measure outlined is not followed and if a corrective action report is not filed, the company is not in compliance for this item.

2. Monitoring procedures not followed.

COMPLIANCE:

Monitoring procedures must be followed to maintain control of the process. If any monitoring procedure has not been followed and a corrective action report is not filed, the company is not in compliance with this item.

3. Corrective action not taken.

COMPLIANCE:

If deviations occur, the company must take corrective action and document it in a corrective action report or Notice of Unusual Occurrence and Corrective Action-(NUOCA.) If a company can demonstrate through other forms of documentation that a corrective action was taken, then it is designated SERIOUS .

SERIOUS: Corrective action taken not as shown in the QTV plan.
CRITICAL: No corrective action.

C. OTHER

1. Modification to QTV plan use without approval.

COMPLIANCE:

Any change in procedures without AMS approval, whether they are written or not, will be considered non-compliance by the company for this item. This includes all procedures at critical control points, sanitation procedures, verification procedures, and consumer complaint procedures. Exceptions will be allowed for those procedures the company can justify that were necessary to avert or control a public safety or health situation provided a corrective action report is on file for the incident and a request for plan modification is filed with AMS within a 24 hour

period.

2. Modification to critical limits without approval.

COMPLIANCE:

No modifications to critical limits will be accepted without prior approval from AMS. Any deviation noted for this item will be considered non-compliance.

SERIOUS: No prior approval but does not lead to unsafe product.
CRITICAL: Has the potential to lead to unsafe product.

3. Certified trained personnel not available.

COMPLIANCE:

Each company must employ a person who has been certified by AMS for this program. At least one HACCP-certified person is required to be present during production. In addition, copies of all certified personnel's certificates must be on file with the company.

4. QTV Plan Prerequisite Programs and/or Procedures not followed.

COMPLIANCE:

Prerequisite programs and/or procedures, including Good Manufacturing Practices, that address operational conditions provide the foundation for the HACCP system. Not following prerequisites means that the system may be compromised and the company is not in compliance for this item.

MAJOR:	not all elements of prerequisite programs are adhered to.
SERIOUS:	criteria for compliance missing with potential to impact QTV program.
CRITICAL:	criteria for compliance missing which will significantly impact QTV program.

Facility Sanitation

1. PEST CONTROL

REASON:

The presence of rodents, insects, and other animals in the facility should not be allowed because they are sources for the contamination of food with foreign material, filth, and bacteria, etc.

1.1 Harborage and attractant areas present.

COMPLIANCE:

The facility and grounds are free of harborage areas. These include but are not limited to: uncut weeds, brush or tall grass; improper storage of unused equipment or materials; presence of litter, waste and refuse; or standing or stagnant water. All garbage and refuse containers are rodent/insect-resistant and outside storage areas are properly constructed.

1.2 Pest control measures not effective.

1.2.1 Exclusion

COMPLIANCE:

Openings to the outside of or within the facility may allow vermin or other pests to enter. Openings and cracks should be screened or otherwise sealed. Screens must be of a mesh not larger than 1/16th of an inch in order to exclude insects. Cracks or holes should be sealed and doors and windows should close tightly (no opening larger than 1/4") to exclude rodents or other animals. Air curtains and strip curtains must be effective. Air curtains shall comply with National Sanitation Standard Number 37 for Air curtains for entrances in food establishments. Strip curtains must run the entire width of the opening with sufficient overlap between flaps (1/2 inch). In addition, every effort should be made to keep birds from areas of the plant where food is transferred or processed.

1.2.2 Extermination

COMPLIANCE:

Birds--Nesting areas must be eliminated.

Insects--There should not be a significant number of insects present in the facility. Insect electrocution devices, when used, must be located near the entranceway. Approved insecticides should be used whenever insect populations become noticeable.

Rodents--There should not be evidence of rodent activity. Evidence of rodents includes, but is not limited to: fecal dropping present; urine stains on bags or walls; slide marks along rodent runways; or feeding areas around stored dry goods bags. The facility should have appropriate rodent control measures in place. If not, the facility is not in compliance.

2. STRUCTURE AND LAYOUT

REASON:

Care must be taken to not allow contamination to enter a food product through non-direct means. Improperly maintained outside conditions can cause contamination to enter the plant through a variety of means, such as airborne (wind), foot traffic, etc. In addition, improper layout of operations within a facility can inadvertently adulterate or contaminate the food product through employee traffic, wind drafts, or other means.

2.1 Grounds condition can permit contamination to enter the facility.

COMPLIANCE:

There shall be no conditions on the grounds such as dusty roads or parking lots, mud puddles, chemical spills, etc., that can cause contamination to be carried into the plant through such means as wind drafts, personnel foot traffic, adherence to personnel clothing, flooding, etc. Design of the facility structure should be such that access is easily obtained to all areas. This is necessary for proper cleaning and sanitizing of floors, walls, and ceilings, as well as for visual inspections.

2.2 Facility.

2.2.1 Design, layout of materials used cannot be readily cleaned and sanitized; does not preclude product contamination or adulteration.
COMPLIANCE:
If the rooms (including restrooms and employee break rooms) in the facility are laid out or designed in such a way that they cannot be readily cleaned or sanitized, then the facility is not in compliance. This would include improper materials for walls, ceilings, etc., as well as hard-to-reach rooms or corners even when the equipment is removed from the room.

2.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated.
COMPLIANCE:
There must be sufficient separation between different activities in the processing, packaging and handling of food products. This includes the complete separation of living/sleeping quarters or heavy maintenance areas from food-handling areas. The food product should flow easily from one stage to another and not be allowed to come into contact with non-food surfaces if exposed. In addition, the layout of the facility should not be such that product contamination is likely due to heavy employee traffic through work areas.

SERIOUS: If insufficient separation between different activities in the processing, packaging and handling of food products are found.

CRITICAL: If the possibility of product contamination exits due to sufficient separation between different activities in the processing, packaging and handling of food products.

2.3 Equipment and utensils' design, construction, location, or materials cannot be readily cleaned and sanitized; does not preclude product contamination or adulteration.
COMPLIANCE:
Any equipment used in the manufacturing or handling of the food product must be designed or constructed so that it can be easily taken apart for regular cleaning and inspection. Failure to do so will cause the facility to be out of compliance. In addition, if the materials used are not of a material suitable for its intended purpose or there is reuse of single-service items, then the facility is also out of compliance.

3. MAINTENANCE
REASON:
Food handling establishments must be maintained at a high level. Deterioration of the building such as a leaky roof, cracks or depressions in the floor, or unprotected glass lighting fixtures can be reservoirs for bacteria or can cause direct contamination of food products being manufactured in the facility. Equipment and utensils that are not well

maintained also pose a risk of bacterial harborage or direct product contamination. Conditions such as rusted or pitted product-contact surfaces and frayed conveyor belts are examples of non-compliance.

3.1 Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.

3.1.1 Areas directly affecting product or packaging material.
COMPLIANCE:
For those areas that will directly affect product or primary packaging materials, (packaging immediately surrounding product), the roof, ceilings, walls, floors, and lighting fixtures must be maintained as designed and lights must be protected. Failure to do so causes the facility to be out of compliance.

SERIOUS: Area is highly objectionable but does not lead to unsafe product.
CRITICAL: Area has the potential to lead to unsafe product.

3.1.2 Other.
COMPLIANCE:
For areas in the facility other than in 3.1.1 above, the roof, ceilings, walls, floors, or lighting fixtures must also be maintained as designed. This does not include those areas designated as offices and in which food products or primary packaging materials in any stage of production will not be handled or stored.

3.2 Insufficient lighting.
COMPLIANCE:
Lighting in areas where food is handled, processed, stored, packaged, or displayed and where sanitation is performed, must be adequate to allow the intended operation to be performed in a sanitary and wholesome manner. Lighting should not be so excessive as to affect the temperature of the product.

3.3 Equipment, primary packaging materials, and utensils not maintained in proper repair or removed when necessary.

3.3.1 Product-contact surfaces.
COMPLIANCE:
All product-contact surfaces must be kept in good repair. If the contact surface cannot be repaired, then the piece of equipment or utensil should be removed so as not to allow for its use. Primary packaging materials should be adequately covered when stored or not in use. Failure to provide these conditions will result in non-compliance.

3.3.2 Other.
COMPLIANCE:

All non-food contact surfaces should also be maintained in good repair. The facility is in non-compliance when the maintenance of all additional equipment or areas of equipment and utensils not referred to in item 3.3.1 above is insufficient and may allow indirect product contamination or adulteration.

4. CLEANING AND SANITIZING

REASON:

A sound cleaning and sanitizing operation is vital to plant and food hygiene. Product-contact surfaces are most important and the most obvious. However, improper cleaning of non-product contact surfaces can cause adulteration or contamination to occur through indirect means. Good housekeeping of all areas including employee locker rooms and restrooms is necessary to allow the auditor proper observance of rooms and areas to determine if they are in fact clean. In addition, the methods used shall be such that the product will not be adulterated or contaminated.

4.1 Product contact surfaces not cleaned or sanitized before use.

COMPLIANCE:

Product contact surfaces must be cleaned using proper techniques to remove dirt and debris. Sanitizer must be used before product contacts the surface. Sanitizing without cleaning is insufficient. Any violation will be considered as not being in compliance.

SERIOUS: if product contact surfaces are not cleaned and sanitized.

CRITICAL: if product contact surfaces are not cleaned and sanitized before use.

4.2 Non-product contact surfaces not cleaned before use.

COMPLIANCE:

Non-product contact areas must also be cleaned prior to use. However, sanitizing is not required. This includes walls, ceilings, floors, and other room areas as well as equipment.

MAJOR: If non-product contact surfaces not cleaned and sanitized.

SERIOUS: If non-product contact surfaces not cleaned and sanitized before use.

4.3 Inadequate housekeeping.

COMPLIANCE:

Any excess clutter in production areas, employee areas, or other areas of the facility will cause the facility to be in non-compliance. This does not include those areas designated as office areas.

MINOR: Excess clutter.

SERIOUS: Excess clutter that is highly objectionable.

4.4 Cleaning methods permit adulteration or contamination.

COMPLIANCE:

Employees must take care to use methods that will not adulterate or contaminate the product. Any cleaning or sanitizing procedures or techniques that may cause the product to become adulterated or contaminated will cause the facility to be in non-compliance. Examples of non-compliance include but are not limited to inadvertent touching of product or product surfaces with wash water, detergent, sanitizer, etc., during production.

5. PERSONNEL

REASON:

A high degree of personnel compliance is necessary for a sanitation program to work properly. The best systems can easily be defeated if the facility personnel do not maintain high ideals in the production and handling of the food product.

5.1 Processing or food handling personnel do not maintain a high degree of personal cleanliness.

COMPLIANCE:

All persons, while in food preparation or handling areas shall wear clean outer garments, use clean cloths, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination or adulteration of food. This includes occasional workers or visitors to the area.

5.2 Processing or food handling personnel do not take necessary precautions to prevent contamination of food.

COMPLIANCE:

All persons, while in a food preparation or handling area, shall:

1. Wash their hands thoroughly to prevent contamination by undesirable microorganisms before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. After washing, the hands must be sanitized using the company-provided hand dip stations.

2. Remove all insecure jewelry, and when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.

3. If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves shall be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved. If gloves are used they will be washed and sanitized at the same frequency as employees hands as described in number one of this list.

4. Wear hair nets, caps, masks, or other effective hair restraint. Other persons that may incidently enter the processing areas shall comply with this requirement.

5. Don't expectorate; nor store clothing or other personal belongings; do not

eat food or drink beverages; nor use tobacco in any form in areas where food or food ingredients are exposed, or in areas used for food processing, storage of food ingredients and/or packaging materials, washing of equipment and utensils, or in production areas.

6. Take other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to: perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

5.3 Controls.

5.3.1 Facility management does not have in effect measures to restrict people with known disease from contaminating the product.
COMPLIANCE:
No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person. Plant management shall require employees to report illness or injury to supervisors.

5.3.2 Hand washing and hand sanitizing stations not present or conveniently located.
COMPLIANCE:
Hand washing and hand sanitizing stations must be present and located conveniently and in sufficient numbers to provide employees ease of their use.

6. RESTROOMS

REASON:
Sufficient restroom facilities and restroom supplies not only provide for the comfort of employees, but are necessary for good, healthy, and wholesome conditions for the production of food.

6.1 Insufficient number of functional toilets.
COMPLIANCE:
The facility must have one operable, in good repair, conveniently accessible toilet per fifteen (15) employees, per gender. For men, urinals may be substituted for toilet bowls, but only to the extent of one-third (1/3) of the total number of bowls required.

6.2 Inadequate supplies.
COMPLIANCE:
The restrooms must provide supplies such as toilet paper, soap, etc., sufficient enough to meet the employee's needs.

7. WATER SUPPLY

REASON:
Process water must be of very high quality as it directly interfaces or becomes part of the product being manufactured. Therefore, no filth, deleterious chemicals, bacteria, or other contaminants may be present in solution as it will directly affect the safety of the product. Available water must pass potability standards established by federal, state, and local authorities. Water that is supplied to the plant must meet certain minimum standards. However, processing water must also be reasonably protected in the facility. Conditions that allow contamination to occur cannot be allowed. These may include cross-connection of plumbing, back-siphonage, or back flow from a contaminated source to the supply system or open vessels of water.

7.1 Unsafe water supply.
COMPLIANCE:
The water supply, including well water, will be in compliance when by certification or direct testing the supply is found to meet the federal standards set forth by the Environmental Protection Agency. Private supplies shall have testing performed a minimum of every six (6) months. Certification of municipal or community systems should be secured at a minimum of once per year.

7.2 No protection against backflow, back-siphonage, or other sources of contamination.
COMPLIANCE:
A facility will be in compliance when all cross-connections are eliminated, backflow prevention devices are installed wherever backflow or siphonage may occur, or where other possible forms of contamination may be present.

7.3 Inadequate supply of hot water.
COMPLIANCE:
Hot water is necessary for many cleaning techniques. In addition, a hot water supply is necessary to provide a comfortable means for employees to wash their hands. If the tap is on and a luke-warm supply of water is present in sufficient quantities to the tasks it will perform in the facility, the plant is in compliance. The supply must also be easily accessible for its proper use.

8. ICE
REASON:
Ice should be made from safe, potable water, and be handled in the same manner as a food product.

8.1 Not manufactured, handled, or used in a sanitary manner.
COMPLIANCE:
A facility will be in compliance when potable water is used for manufacturing, when the manufacturing equipment is clean, and the ice only touches impervious surfaces; the ice holding containers are clean and made of appropriate impervious material; handling equipment is clean and appropriate for food contact; and ice is not reused on ready-to-eat product. For facilities receiving ice from an outside supply, a certificate of conformance will be necessary to ensure that the ice being received meets the standards set forth in this document. In addition, potability

checks must be made at a minimum of every six (6) months on ice received.

SERIOUS: If the ice is not manufactured, handled, or used in a sanitary manner and doesn't come in contact with the product.

CRITICAL: If the ice is not manufactured, handled, or used in a sanitary manner and comes in contact with the product.

9. CHEMICALS

REASON:
Plant chemicals are cleaners, sanitizers, rodenticides, insecticides, machine lubricants, etc. They must be used according to manufacturer's instructions, have proper labeling, and be stored in a safe manner or they may pose a risk of contaminating the food product that the establishment is handling or manufacturing.

COMPLIANCE:
A facility will be in compliance when the chemicals are used according to manufacturer's instructions and recommendations and stored in an area of limited access away from food handling or manufacturing. All chemicals must be labeled to show the name of the manufacturer, instructions for use, and the appropriate EPA or USDA approval.

9.1 Chemical(s) improperly used or handled.

SERIOUS: Chemicals improperly used or handled but will not result in unsafe product

CRITICAL: Chemicals improperly used or handled with potential to lead to unsafe product.

9.2 Chemical(s) improperly labeled.

9.3 Chemical(s) improperly stored.

10 VENTILATION

REASON:
The lack of proper ventilation in a facility may cause condensation or foul odors to occur. Both are due to inadequate air exchange in the building. Condensation in a plant environment may cause filth, bacteria, or other contaminants to adulterate food products through drippage on exposed food, processing equipment, or packaging material. Foul odors normally reveal the presence of bacterial activity within the plant.

10.1 Condensation.

10.1.1 Areas directly affecting product or primary packaging material.

COMPLIANCE:
If any condensation is found in areas in the facility where the condensation has the potential to come in contact with product or primary packaging material, the facility is in non-compliance.

SERIOUS: Area is highly objectionable but does not lead to unsafe product.
CRITICAL: Area has the potential to lead to unsafe product.

10.1.2 Adequate air exchange does not exist.
COMPLIANCE:
A facility is in compliance when adequate air exchange exists to preclude the development of foul odors.

11. WASTE DISPOSAL

REASON:
In a manufacturing environment raw material is either utilized in the product or is discarded as waste which may be eliminated via the sewerage system or physically removed. Sewage should be regarded as anything that accesses the sewerage system including bodily wastes, process water, etc. Any failure to eliminate these wastes allows fecal and other human disease organisms to possibly contaminate the food product through splash, foot traffic, or other means. Processing waste is likely to carry filth, decompose quickly, and be an attractant to rodents, insects, and other vermin.

11.1 Improper disposal of:

11.1.1 Sewage.
COMPLIANCE:
A facility is in compliance when sewage systems drain properly, are vented to the outside, and are connected to an approved private septic system or a public septic and/or sewerage system.

SERIOUS: Systems are highly objectionable but does not lead to unsafe product.
CRITICAL: Systems have the potential to lead to unsafe product.

11.1.2 Processing waste.
COMPLIANCE:
A facility is in compliance with regard to processing wastes when they place the waste in proper containers, placed at appropriate locations throughout the plant, and removed frequently.

Appendix C

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